

Sergeant Derenda was there to act because he volunteered to drive the lead vehicle, knowing the likely danger inherent in his choice. He stepped forward because most of his fellow soldiers had wives and children at home. This final heroic act defined who Robert was, how he lived, and how he served the country he loved.

For his valorous actions as a soldier, Sergeant Derenda was made an honorary Green Beret, and he received numerous awards and medals including the Purple Heart and the Silver Star.

Not only did the Army name a building after him in Fort Dix, NJ, but a street also bears his name in his hometown of Cheektowaga, a suburb of Buffalo, NY.

Robert graduated from the State University of New York at Buffalo with a degree in psychology. No doubt that degree, combined with his long history of military service, is what molded him into a superb drill sergeant. At Robert's funeral, MG Bruce E. Robinson called him a "natural" at whipping young men into fighting shape.

After graduation, Robert served on active duty with the Army for 6 years. He returned to his alma mater and earned a chemical engineering degree while serving in the Army Reserve.

It was his work as an engineer that brought him to Calvert City, KY, leading Robert to live in nearby Ledbetter and call the Bluegrass State home.

However, this outstanding leader was shaped by more than the work that he so enjoyed. A cross-country runner in high school, Robert would return to his parents' home in New York each Thanksgiving to run in the annual Turkey Trot. When he wasn't running, you might see Robert on his Harley-Davidson motorcycle, cruising around town.

Robert was also a deeply religious man. A fellow soldier described him as a "good Catholic boy," and his priest, the Reverend Theodore C. Rog, said simply that when it came to Robert's faith, "He lived it."

Robert also cherished his relationship with his two nephews, Nicholas and Thomas Kibby. Although his sister, Caroline Kibby, raised her family in a town near Pittsburgh, Robert remained close. He left his entire estate to Caroline, but told her that should anything happen to him, it was all to go to her boys.

His devotion to them, however, went deeper than any material wealth that he could offer. Robert told Caroline that the reason he wanted to go to Iraq with the Army was to make the world a safer place for Nicholas and Thomas. He understood the dangers that lurked in the world, and wanted his nephews never to know such evil.

Robert's beloved family members include his father, Valerian, his mother, Loretta, his sister, Caroline Kibby, his brother-in-law, Scott Kibby, and his two nephews, Nicholas and Thomas Kibby. I ask the entire Senate to keep them in your thoughts and prayers. I know they will be in mine.

No plaque or street name can heal the tragic loss of the Derenda family after their beloved son, brother, and uncle has been taken from them.

But there are two boys growing up near Pittsburgh right now who will always remember the example their uncle set for them.

And a lifetime of family, friends, and fellow soldiers will be inspired by SFC Robert V. Derenda's noble act of sacrifice. Such examples are worth far more than any bronze plaque could ever be.

I yield the floor.

I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. BROWN. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

CONCLUSION OF MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The ACTING PRESIDENT pro tempore. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The bill clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Landrieu amendment No. 1004, to require the Food and Drug Administration to permit the sale of baby turtles as pets so long as the seller uses proven methods to effectively treat salmonella.

Stabenow amendment No. 1011, to insert provisions related to citizens petitions.

Brown (for Brownback/Brown) amendment No. 985, to establish a priority drug review process to encourage treatments of tropical diseases.

Vitter amendment No. 983, to require counterfeit-resistant technologies for prescription drugs.

Inhofe amendment No. 988, to protect children and their parents from being coerced into administering a controlled substance in order to attend school.

Gregg/Coleman amendment No. 993, to provide for the regulation of Internet pharmacies.

The ACTING PRESIDENT pro tempore. The Senator from Ohio.

Mr. BROWN. Mr. President, we continue the discussion today on S. 1082. I am joined by Senator ENZI as a cosponsor of that bill, with Senator KENNEDY. We are considering several amendments this morning that are designed to and will increase access to lifesaving prescription drugs. I wish for a moment to talk about a couple of those amendments.

One is the Stabenow/Thune amendment No. 1011, cosponsored by Senator LOTT of Mississippi and by me, which will stop drug companies from intentionally jamming up the Food and Drug Administration approval process for generic drugs, exploiting the citizen petition process to block price competition in the marketplace.

Free market economies rely on price competition. When brand-name drug companies block price competition, they are not only cheating generic drug manufacturers, they are cheating consumers, businesses, and tax-funded health care programs. None of us can afford that.

The Congressional Budget Office estimates the Stabenow amendment will save taxpayers hundreds of millions of dollars over the next 10 years. Those are just the savings that accrue to tax-funded health programs. There will also be significant savings to consumers and employer-sponsored health plans.

This amendment preserves the rights, as we should, of citizens to petition their government. But it stops the gaming of the patent system by the name-brand drug companies which have very effectively stymied price competition. I think unanimously in this body we support the whole idea of price competition.

The savings of this bill will go to seniors and others who have seen large out-of-pocket expenses in their purchase of prescription drugs. The savings will go to businesses helping us globally compete better than we might otherwise. The savings will go to taxpayers, through a variety of different Government programs that help people buy their prescription drugs. So every Member's support is crucial on the Stabenow-Thune amendment.

I want to highlight an amendment that has been offered by my colleague Senator BROWNBACK and myself. According to the World Health Organization, more than 1 billion people—nearly one in every six people worldwide—are affected by at least one neglected tropical disease. In addition, neglected tropical diseases claim roughly 500,000 lives each year.

However, less than 1 percent of the 1,400 drugs registered between 1975 and 1999—over a 25-year-period—fewer than 1 percent of the 1,400 drugs registered treated such diseases.

This disparity is clearly due to the lack of financial incentive for pharmaceutical companies to bring neglected tropical disease treatments to market because these diseases disproportionately affect low-income countries, with the poorest of the poor in those countries needing those medicines, most of them in Africa.

Creating incentives for companies to invest in treatments for these diseases is not only in our country's national interest, but it is consistent with our longstanding tradition of caring for those who are less fortunate around the world. In other words, it is consistent with American values.

Senator BROWBACK's and my amendment would award a priority review voucher to any company that brings a neglected tropical disease treatment to market. Priority review is an existing FDA process by which drugs are reviewed in 6 months, as opposed to the average review time of 18 months, significantly speeding the process.

The priority review voucher would be transferrable and could be applied to any drug in a company's pipeline. This amendment will help to bring about research and new drugs treating these tropical diseases and speed the process of getting them to market.

This voucher, which would be worth hundreds of millions of dollars for a company with a new blockbuster drug, would also benefit consumers. That is because it would give consumers earlier access to a new prescription drug. Most importantly, creating incentives for pharmaceutical companies to develop and to manufacture neglected and tropical disease treatments will save lives.

I commend Senator BROWBACK for his work on behalf of impoverished populations who desperately need our attention. He is offering Members of this body an opportunity to simultaneously save lives in developing nations, give U.S. consumers access to new medicines more quickly, and engage the drug industry in a win-win proposition.

It is a rare opportunity. I urge Members on both sides of the aisle to support the Brownback-Brown amendment.

I yield the floor and suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The bill clerk proceeded to call the roll.

The ACTING PRESIDENT pro tempore. The Senator from North Dakota is recognized.

Mr. DORGAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. DORGAN. Mr. President, the Cochran amendment requires a certification by the Secretary of Health and Human Services which we know from previous experience now cannot or will not be made by the Secretary of Health and Human Services.

Therefore, I was going to ask the Senator from Wyoming a couple of questions, if at some point he might come back so I can engage him in a colloquy.

The point of the Cochran amendment is that it will now nullify the entire amendment that was offered by myself, Senator SNOWE, and 33 other Senators who had cosponsored the amendment. I wanted to point out that in the amendment, it not only allowed for reimportation of prescription drugs—FDA-approved prescription drugs from other countries whose chain of custody

was identical or virtually identical to ours so that the American people would have access to lower priced, FDA-approved prescription drugs—but we also included in that amendment, which would now be nullified because the Secretary of HHS will not be able to certify, counterfeit-resistant technologies.

Now, I believe those counterfeit-resistant technologies are as applicable to our existing drug supply domestically as they are to any potential imports that would be brought into this country.

I want to read just a couple of comments about this. Then I would like, if the Senator from Wyoming would be willing, to entertain some questions or at least engage in a colloquy on this subject. I would like to discuss with him the provisions in the bill that would be nullified by Senator COCHRAN's amendment because the Secretary could not certify, and so all of the amendments that we offered would be nullified. The provisions dealing with counterfeit-resistant technologies, it seems to me, probably should proceed because all of us are concerned about the issue of counterfeit drugs, whether it is through reimportation or counterfeit drugs in the existing drug supply.

All of the discussions about counterfeit drugs that have been had on the floor of the Senate have nothing to do with reimportation; it has to do with the existing circumstances. So the counterfeit-resistant technologies, that portion of the amendment—which will also now be nullified—I think should be restored. I have offered a second-degree amendment to do that, simply to restore for the current drug supply in this country the safety provisions that would exist with respect to the counterfeit-resistant technologies.

Let me read it for a moment. The provisions in the amendment were, the packaging of any prescription drugs would incorporate, one, a standardized numerical identifier unique to each package of such drug applied at the point of manufacturing and repackaging, in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing; and, two, overt optically variable, counterfeit-resistant technologies that are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners, similar to that used by the Bureau of Engraving and Printing to secure U.S. currency, that are manufactured and distributed in a highly secure, tightly controlled environment.

But the point is, I held up a twenty-dollar bill yesterday on the floor of the Senate and said: This has designed into it—the architecture of this counterfeit-resistant bill has designed into it a lot of protections in order to prevent counterfeiting of the twenty-dollar bill.

We are all concerned about the counterfeiting of prescription drugs, so we

have put a provision in the amendment that we had offered, something called counterfeit-resistant technology. My point is, it seems to me we should at least make that apply to the domestic drug supply, even if we have already made a decision we are going to nullify the opportunity for reimportation.

We will come back to that decision later. The Senate will debate that again and vote on that again. But for now, at least, it seems to me we should not lose the provisions of that amendment dealing with counterfeit-resistant technologies.

Might I ask the Senator from Wyoming, the ranking member on the committee, his feeling about adding that provision that would, I think, substantially safeguard the domestic drug supply?

Mr. ENZI. Mr. President, I appreciate the question. I appreciate the effort that has gone into adding ways the drug supply can be more safe in the United States. Of course, we are interested in that. The primary focus of the bill was to make sure the U.S. drug supply was as safe as possible.

There were a number of amendments, one of which was withdrawn last night, that dealt with Internet sales. That could have been Internet sales in the United States as well as Internet sales outside of the United States. The reason it was withdrawn is the sponsor of it did not want it to get polarized into a debate as to whether that would undo what you have been working on. It was not. It was to add some more safety and security.

Senator KENNEDY and I have been working on this FDA bill for over 2½ years now. We also have been working on some things that deal with pedigree and licensure in the United States as well as outside of the United States. We did not put that in. We didn't want it to be something, again, that would polarize people and maybe distract from being able to do it at a very logical time.

So most of our effort right now is to make sure we do not enter into some budget points of order, that we are able to accomplish the bill and get it to conference where additional changes will be made.

Our committee works maybe differently from others; I am not sure. I know it works differently from the Banking Committee that I also serve on. It has been one of the most contentious committees in the Senate. But over the last 2½ years we have changed that perspective a bit and really accomplished a lot.

One of the biggest changes we have had is the way that we do a bill. Before we tried to stuff it at every possible opportunity; that meant in committee as well. You will notice this bill had only 1 day of markup. That is phenomenal for that committee. Three days a week is not unusual for the committee. We got it out of there in 1 week, which helped us to understand the concerns of the people on the committee.

We promised to work on that when it went to the Senate floor. We have worked on it after it came to the floor. More amendments have been put in. We have worked with people. Senator DURBIN had one on food safety. We worked with him and got that in; anything that does not appear to polarize, does not appear to add budget points of order, and things that have been considered before, we are trying to work into this bill. New concepts, we would like to talk about them a little bit more, explore them a little bit more, but we want everything to be as safe as possible. That is what we are working for.

There are some huge costs that may potentially be involved in what you are talking about there. If the costs add to the costs of drugs, then someone has to pay it. Then, perhaps, we will be making less access to drugs. We do not want that, and I know you don't want that. Your focus has been on getting lower cost drugs to everyone.

It is the same with the amendment that Senator STABENOW has. We have worked on that for days. It is a concept that we have been working on before and held some hearings on. I think we have arrived at some compromises to put that in. We are trying to wind up with some bipartisan things that we can do to get it to conference where more can be done. And some of these issues we have revisited.

We are one of the busy committees on the Hill. We are holding a hearing as we speak. I had to leave that to come over to the floor to do just exactly this.

I appreciate the Senator's efforts and ideas and creativity. I hope he will work with us.

Mr. DORGAN. I thank the Senator from Wyoming for his response. It is true the bill on the floor of the Senate is a bill dealing with drug safety. But I think it is also the case that a lot of the discussion on the floor of the Senate has been about counterfeiting and about the potential danger counterfeiting would pose with respect to reimportation, and also the danger counterfeiting poses with respect to the existing drug supply.

If that is the case, it seems illogical to me not to include pedigrees and serial numbers and RFID technology and the latest counterfeit technology in this bill. What we had done with 33 of us cosponsoring the reimportation bill is, we understood with respect to reimportation you need to be sure it is safe before you proceed.

So we drafted a section on that, consulting with all of the experts. We spent a lot of time on it. We have worked on it for a couple of years now. That section, it seems to me, would vastly improve the underlying bill. Maybe it is not a consensus. I understand the pharmaceutical industry does not want to do pedigree and serial numbers, and so on, the way we have described it. But it seems to me it certainly should be the case that we add

as much as we can to this bill—not load it down but add as much as we can on the issue of protecting against counterfeit drugs, whether it is through reimportation or the domestic drug supply.

I guess I do not quite understand—I don't believe there is a budget point of order. I don't believe we are talking about any dramatic new costs. In any event, I would expect we should not have a tradeoff of a less safe drug supply versus the cost of the drug. I think all of us want the same thing. I believe Senator KENNEDY and Senator ENZI would both want the safest possible drug supply we could have.

Again, I come back to this notion of, we spend a lot of time worrying about how to detect a counterfeit twenty-dollar bill, and we have engineered substantial safety precautions. Why should we not do the same with respect to this bottle of Lipitor, if I might have consent to show it again.

This is produced in Ireland. It contains a 20-milligram tablet of Lipitor to lower cholesterol. Why would we not want something on this bottle from the manufacturer that gives us the opportunity to understand the pedigree, the serial number, and so on? There are some markings on it, but we can do much better. That is the purpose of my offering a second-degree amendment, to preserve the counterfeiting and safety standard a bipartisan group of us has created. I would be happy to yield for a response if the Senator wishes.

Mr. ENZI. Mr. President, I would like to respond.

I like his example of the twenty-dollar bill or any other denomination. This has nothing to do with the pharmaceutical companies. This is a discussion Senator KENNEDY and I have had ongoing for a long time, and we brought in some technical people to figure out how we can provide that security in a number of different ways. The way that differs from the twenty-dollar bill is that for everybody who handles—not everybody, most people—twenty-dollar bills on a regular basis, the same design stays in play for a long time. But with the pill bottle, maybe the first pill bottle one gets will be the only pill bottle. Having the knowledge of what exactly to look for on there is not something we teach in school or in pharmacies or anywhere else. It has to be something that people can tell whether it truly is. That is what adds to the cost when it comes to pharmaceuticals. We are looking at inventors who are coming up with different ways all the time to make things secure, not just medicines. We haven't found the answer yet.

Mr. DORGAN. Might I ask the question, are you moving in your committee toward requiring a pedigree and serial numbers? Is that where you are going to move in committee to have consensus? That is what I understand.

Mr. ENZI. Mr. President, that is correct. We have been working on a pedigree and licensure amendment—it is

actually structured as a separate bill—in anticipation of trying to add to this when we can find a solution that we feel comfortable with, and we haven't gotten there yet. I think we are close, but we haven't gotten there yet. It has been a joint effort with Senator KENNEDY and I and both our staffs.

Mr. DORGAN. Mr. President, if I may further, this is the first I understand that there is an issue with the anticounterfeit measures we have put in our reimportation bill. We have the counterfeit-resistant technologies that we have put in the bill. I guess if I hear the Senator from Wyoming correctly, he is not comfortable with those at this point. I had thought the issue was generally the philosophy of reimportation and pricing. Then I think we have a deeper chasm than I expected. I thought there was generally consensus that the technology that now exists, whether it is RFID or lots of new things that are available, the technology that exists should be used with respect to the latest available technology to resist counterfeiting. I thought there was perhaps a consensus on that. Maybe I was wrong. If there is a disagreement about whether we should have standardized identifiers, then I suppose there should be some hearings on that. I had thought we were beyond that point.

That was the purpose of my offering a second-degree amendment. I did not expect it would be controversial to apply, whether it is to the domestic drug supply or the potential reimportation at some future point, the counterfeit-resistant technologies that already exist to be made available if we simply require it.

Mr. ENZI. Mr. President, another technicality that we work on on this and a principle we have established that works well for the committee is we try not to be ultraspecific on what we are doing so that we are picking winners and losers. That is a difficulty we had with the amendment the Senator proposed as well. Not that it can't be worked with and come up with something that fits the criteria of the principle. One of the difficulties of debating things on the floor as a new amendment and unamendable is that usually there are other ideas, some principles, other ways of working with it that are very difficult to do from the floor standpoint.

That is why we start with the mark-up and some of the other things and keep working with them. I think you have to admit this has been pretty progressive in trying to get something done. There hasn't been the effort to stall things out. There has been a lot of opportunities to do that, but we have been trying to keep things going and hope to get something finished up on this bill so it can get to conference.

Mr. DORGAN. Mr. President, I certainly don't intend to stall this bill. This legislation is going to pass. I indicated yesterday I wanted to see what was in the managers' package. Several

of the proposed amendments, even at that point when I saw the package, were still under some reform or some change. Having reviewed it now, I can tell my colleagues I have no difficulty with the baby turtle provision, the pet baby turtle provision. I considered that at great length last night. I stayed awake considering it. But I decided to support the baby turtle provision and the tanning bed provision, for that matter, along with ginseng. I understand these are things that are being adjusted in the managers' package.

I have looked through it. I don't have a problem with the specifics of the managers' package. My issue today was to come to talk about the counterfeit-resistant technologies that will be available to fight the issue of counterfeit drugs. The reason I felt it important to do that, most of the discussion to defeat the Dorgan-Snowe amendment and to impose the Cochran amendment was because of the discussion on the floor, what if we get counterfeit drugs under this proposal. So the discussion was all about not the counterfeit drugs that have come in under the proposal but the counterfeit drugs that have already come in under existing circumstances. My thought is, if counterfeiting is a big problem, then the underlying bill dealing with drug safety should have the strongest possible provisions relating to counterfeit-resistant technologies. That is regrettable not the case.

I will end up voting for this bill when we get to final passage because it is a step forward. But it is not out there where it ought to be with respect to counterfeit-resistant technologies. I understand part of the reason is the pharmaceutical industry is not supportive of moving as far as we should move. At any rate, I appreciate the Senator responding to me. Frankly, it is fine on the floor to have a discussion. I don't think all discussion ought to be somewhere in committee. We ought to have pretty interesting discussions on the floor about what is in a bill and what is not, what we ought to add that would improve it. But I appreciate the Senator from Wyoming responding to me. As I indicated, I have a second-degree amendment along with a couple of others.

I yield the floor.

The PRESIDING OFFICER (Mr. CASEY). The Senator from Ohio.

Mr. BROWN. Mr. President, Senator DORGAN is offering an important compromise. He is saying we should at least preserve the drug safety provisions in his reimportation amendment. These provisions are the result of significant discussion with public safety experts, and I believe the Senate should support the Dorgan amendment. Whether we agree on the issue of reimportation—and there is clearly a split in this body—we do agree on the importance of safety in our domestic supply. There have clearly been attempts to counterfeit inside the domestic supply. The Dorgan amendment

brings us to a place that can help us answer those questions. I think the opponents to reimportation are wrong, but I understand they raise issues of drug safety. Those same issues of counterfeiting are present in our domestic supply, as Senator DORGAN said, under the law, under the situation we are in today.

It sort of begs the larger question of drug safety overall. One of the worst ways we compromise drug safety is by limiting access to affordable prescription drugs. That limitation of access is because of the high cost of prescription drugs. Too many of us know of situations where people have said to me, in Zanesville and Lima and Toledo and Cleveland: I had to cut a prescription in half so they last twice as long or I took the pills every other day. Until we can find ways, which this bill takes some steps in that direction with the citizen petition process and other things, of getting lower cost prescription drugs into people's hands when their doctors prescribe them, the reimportation issue was one way we could have done that better. I am hopeful we can work with Senator DORGAN on some of these issues to bring us to the point that we are satisfied that the domestic supply for prescription drugs is as safe as it can be.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I thank the Senator from Ohio for his comments. But I wish to give a little bit more of an answer to the Senator from North Dakota, who has invested a lot of time and effort over the years in a variety of these issues that deal with the safety of our drug supply. I have to tell him, we got his second-degree amendment. Anything we have had has been a very cursory look. We are willing to sit down. We hope his staff will sit down with my staff and take a look at it and see what can be done.

Mr. DORGAN. Might I point out, the second-degree amendment is language taken out of the Dorgan-Snowe bill that we filed months and months ago. It is identical language with respect to counterfeit-resistant technology. It is not new language.

Mr. ENZI. Mr. President, I am hoping that since we did not have a chance on drug importation—and I wish to make the point that that is importation, not reimportation—we didn't have a chance to sit down and work on that and work through it and see what changes could be made, it would only be logical that for a portion of that, we probably ought to sit down and look at it. We are never sure on a second-degree amendment whether it is exactly the same, but we didn't have the opportunity to work on it with the Senator. I think all the staffs that have been working on this have been working in a bipartisan way to come up with a solution. We will take a look at that specifically and see what can be done with it.

I yield the floor.

The PRESIDING OFFICER. The assistant majority leader.

Mr. DURBIN. Mr. President, I have an amendment which I filed last week with Senator BINGAMAN on conflict-of-interest issues before the advisory committees of the Food and Drug Administration. I understand there may be an objection—I hope there is not—to setting aside the pending amendment and calling this one up for consideration. I don't want to catch anyone off guard with my request. I hope the Senator from Wyoming will note what I am about to request. If it is not consistent with his current wishes, I am asking unanimous consent that the pending amendment be set aside and that we move to amendment No. 1034 which I have filed at the desk.

The PRESIDING OFFICER. Is there objection?

Mr. ENZI. Reserving the right to object, there are several other people in that same position of wanting to call up amendments. We are trying to come up with a logical order, so I do object.

The PRESIDING OFFICER. Objection is heard.

Mr. DURBIN. I thank the Senator. I wouldn't take it personally. The issue I am raising here needs to be dispelled.

What is the Food and Drug Administration? It is a relatively small Federal agency with a huge responsibility. We spend about \$1.7 billion a year on the Food and Drug Administration in a huge Federal budget. This tiny agency is responsible for the safety of about 25 percent of all that we purchase as Americans. They have responsibility when it comes to drugs, devices, biologics, food, veterinary medicines, all sorts of things, equipment. This small agency has a huge responsibility. We give them more and more things to do, and we trust the integrity of the Food and Drug Administration. We believe the Food and Drug Administration giving its approval means something. We can trust it. They have reached a decision that something we are about to buy is safe and effective. For most Americans, that is the seal of approval.

How do they reach that level of integrity? They set up advisory committees. These are the wisest men and women they can find who take a close look at each one of the things they review and inspect to determine whether they truly are safe and effective. It is kind of a jury. The jury may be 10, 20, 30 different people who sit and make a decision.

These decisions are critically important. I don't think I overstate it when I say these decisions are life-and-death decisions. They will decide that a certain pill which a pharmaceutical company says will help you with your heart condition, in fact, is safe to take and is effective, it will do what it is supposed to do. If they make a bad decision and the pill is not safe, a person's health can be jeopardized. So truly these are life-and-death decisions the advisory committees make at the

Food and Drug Administration. In addition, these are very important economic decisions. Giving the seal of approval for a new drug means for that drug company the potential of making millions, if not billions, of dollars. So the stakes are high. Each time the advisory committee makes a decision, they know lives are on the line, and they also know a thumbs-up and a decision of approval can mean the stock of this company is going to rise, their profits will rise, they will make more money for shareholders, and they will have more money for research. It is a big undertaking.

So it is not unfair for us to ask: Who are the people who sit on these advisory committees? Who are the people who are the jurors who try to impartially look at these issues and decide what is best for the American people?

Well, it turns out we have had some problems—some significant problems—in the past. One would think it would be obvious to us that we don't want to appoint people to sit on the juries, on the advisory committees, who have a conflict of interest. What about someone who is on the payroll of the pharmaceutical company that wants a drug approved; would you want that person sitting on the advisory committee? What about someone who has earned \$50,000 coincidentally speaking to this company's annual retreat in some Caribbean island; would you want that person on the advisory committee? What about someone who is on the payroll receiving money from a company that can stand to make millions of dollars if the decision goes the right way? The natural human reaction is: Well, shouldn't those people sit somewhere else? They shouldn't really be in the room if we are talking about their employer, if we are talking about someone who has paid them money. They shouldn't be part of this, should they? We want people sitting in that room who don't have any conflict of interest or any vested interest in the decision. We want people who are truly objective, dispassionate, and truthful. I think most Americans would agree. That is pretty obvious.

Well, it turns out that over time the Food and Drug Administration got a little bit lax, a little bit sloppy. Back 7 or 8 years ago, USA Today published a dramatic expose about these advisory committees. They came to the conclusion that the experts sitting on these advisory committees who were supposed to be independent many times had a direct financial interest in the decision they were about to make. How often did it occur? In 92 percent of the advisory committee meetings—this goes back 7 or 8 years now, but in 92 percent of the meetings, at least one member sitting in that room deliberating had a financial conflict of interest. At more than half of the meetings, half or more of the members of the committee had a conflict of interest. What difference does it make? Does it make any difference if the person de-

ciding the fate of a product that means profit or loss for a major corporation is on the payroll of that corporation? I think it does. It turns out it was a problem then, which the Food and Drug Administration started to address but, unfortunately, has not addressed effectively.

Last week, a study by the New England Journal of Medicine, widely recognized and respected, examined the pharmaceutical industry's financial ties to doctors. Here is what they found:

More than one-third of doctors report being reimbursed by the drug industry for the cost of attending professional meetings and continuing medical education; and almost 30 percent said they had been paid for consulting, giving lectures, or signing up patients for clinical trials.

So when it comes to doctors in general, it turns out that a third of them have a conflict of interest. So any patient walking into a doctor's office and the doctor says: You know, I think you should take XYZ drug, you would like to believe that doctor made that decision because they think that is the best drug for you or a member of your family. It is worrisome that in some instances, these doctors have a conflict of interest.

The New England Journal of Medicine also went on to say, in the words of a prominent Harvard expert, Jerry Avorn, the "penetration of commerce into the province of science" causes great concern. It is the same issue here when it comes to these advisory committees.

Now, the argument that comes back from the FDA and from the pharmaceutical industry is there just aren't enough smart people out there. We have to turn our employees and people we have on the payroll and people we have paid money to into these advisory committees because there aren't enough good people out there to sit on these advisory committees.

Well, I think the New York Times made a good observation when it comes to that. Here is what they said:

Unless the Food and Drug Administration makes a more aggressive effort to find unbiased experts or medical researchers to start severing their ties with industry, a whiff of bias may taint the verdicts of many advisory panels.

Here is what they have found over and over again: These conflicts of interest can cause a problem.

Let's be very specific. In February of 2005, an FDA advisory committee considering the painkillers Vioxx, Bextra, and Celebrex, whether they should be sold to the public. There were 10 scientists sitting on that advisory committee who had conflicts of interest. They had some financial connection with the companies that made the products they were judging. Had the votes of those 10 scientists been excluded because of their conflicts of interest, the panel would have favored withdrawing Bextra from the market and blocking the return of Vioxx. Instead, with the 10 conflicted scientists

and experts, they voted that the drugs return to the market. These drugs were very dangerous. People were having heart problems and other medical difficulties. They should never have been brought back to the market.

What impact did the presence of these people with conflicts of interest have on the deliberations? It could not have been positive. It could not have been objective. They came to this with some financial interest, at least in the companies that were affected by the decision.

Here is what my amendment does. The amendment says the Food and Drug Administration would be limited to only one waiver per advisory committee meeting.

Mr. President, I understand under a previous consent order that we are moving at 12:15 to the consideration of a judge who will be voted on in 20 minutes, Judge Kapala of Illinois. I would like to have the time start on that. I ask unanimous consent to close my remarks on my amendment, say a few words about Judge Kapala, and then the remaining 10 minutes for Senator SPECTER to speak.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. DURBIN. Mr. President, I will be very brief because I see Senator SPECTER is on the floor.

So what I am trying to do is make sure we only have one waiver per meeting, one person sitting on that advisory committee per meeting who might have a conflict of interest.

We go on to say that any person with a financial interest could provide information to an Advisory Committee but can't be participating in or voting on the final decision. I think that only makes sense.

The third thing we say is that the Food and Drug Administration has to actively promote more objective scientific experts without conflicts of interest.

I don't think this is a radical proposal. Don't we want peace of mind at the end of the day that the advisory committee has made a decision based on science and medicine and what is good for America as opposed to the bottom-line profit-and-loss statement of the pharmaceutical company?

There is a lot of discussion on this floor about the safety of drugs and the products that the FDA considers. I hope this amendment, which is critical to the integrity of the FDA, is approved by my colleagues on a bipartisan basis. I hope to offer this amendment tomorrow after we have gone through this rough procedural patch.